

## **REMARKS**

Reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance. The Examiner is thanked for the courtesies extended during the telephonic interview of September 17, 2009.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-11 are under consideration in this application. Claim 1-4 and 6-11 have been amended solely to expedite prosecution of the pending claims and for clarity. In accordance with matters discussed during the telephonic interview of September 17, 2009, claim 1 has been amended to replace the transitional term “comprising” with a transitional phrase “consisting essentially of”. Claims 2 and 7 have been rewritten in an independent form. Support for the amendments can be found throughout the specification and in the claims as originally filed. No new matter has been added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to round out the scope of protection to which Applicants are entitled.

By using the transitional term “consisting essentially of”, the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. MPEP §2111.03. *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). Claim 1 previously called for “[a] stable formulation suitable for administration to animals comprising a combination of two active ingredients and a pyrrolidone solvent wherein the said combination of two active ingredients consists of levamisole and an avermectin or a levamisole and a milbemycin”. There is no intention to create any estoppel as to equivalents, and the “consisting essentially of” transition should be construed to permit additional unlisted ingredients that do not affect the novelty of the combination of levamisole and an avermectin or levamisole and a milbemycin dissolved in pyrrolidone solvent, but to exclude Sorensen et al., and hence render the

claims novel and nonobvious over Sorensen et al., alone or in combination with Komer, Harvey or Huet, et al. and Harvey.

The Examiner is thanked for withdrawing the rejections under 35 U.S.C. § 112, first and second paragraphs, the rejection of claims 1, 3-5 and 7-10 under 35 U.S.C. § 102(b) as being anticipated by Komer (U.S. Patent No. 5,773,422), and the rejection of claims 1, 2, 6, and 11 under 35 U.S.C. § 103(a) as being unpatentable over Komer in view of Huet, et al. (U.S. Patent No. 6,426,233), Harvey (U.S. Patent 6,165,987), and Harvey (GB Patent Application No. 2 252 730).

Furthermore, the present amendments to the claims do not add any subject matter that has not already been considered by the Examiner. Therefore, Applicants respectfully request entry of the amendments and reconsideration of the claims.

The issues raised by the Examiner in the Office Action and Advisory Action are addressed below in the order they appear in the prior Action.

## **II. THE REJECTIONS UNDER 35 U.S.C. §§102 AND 103 ARE OVERCOME**

Claims 1, 3-8, and 10 remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Sorensen et al. (WO 01/05232).

Claim 2 remains rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sorensen et al. (WO 01/05232) as applied to claims 1, 3-8, and 10, and in further view of Huet et al. (U.S. Patent No. 6,426,233) and Harvey (U.S. Patent No.6,165,987).

Claim 9 remains rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sorensen et al. (WO 01/05232) as applied to claims 1, 3-8, and 10, and in further view of Komer (U.S. Patent No.5,773,422).

Claim 11 remains rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sorensen et al. (WO 01/05232) as applied to claims 1, 3-8, and 10, and in further view of Harvey (U.S. Patent No.6,165,987).

Applicants respectfully disagree and traverse the rejections.

By using the transitional term “consisting essentially of”, the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. MPEP §2111.03. *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). Claim 1

previously called for “[a] stable formulation suitable for administration to animals comprising a combination of two active ingredients and a pyrrolidone solvent wherein the said combination of two active ingredients consists of levamisole and an avermectin or a levamisole and a milbemycin”. There is no intention to create any estoppel as to equivalents, and the “consisting essentially of” transition should be construed to permit additional unlisted ingredients that do not affect the novelty of the combination of levamisole and an avermectin or levamisole and a milbemycin dissolved in pyrrolidone solvent, but to exclude Sorensen et al., and hence render the claims novel and nonobvious over Sorensen et al., alone or in combination with Komer, Harvey or Huet et al. and Harvey.

Specifically, there is no teaching or suggestion of the now claimed invention, e.g., no teaching or suggestion in Sorensen et al. of a combination of levamisole and an avermectin or levamisole and a milbemycin in a pyrrolidone solvent, in the absence of a benzimidazole.

There is no teaching or suggestion in Huet et al., Harvey and Komer of the presently claimed composition. As discussed previously in the reply of record filed August 3, 2009, none of Huet et al., Harvey nor Komer teach or suggest a formulation comprising a combination of levamisole and an avermectin or levamisole and a milbemycin in a pyrrolidone solvent.

Therefore, none of Sorensen et al. alone or in any combination with Komer, Harvey or Huet et al. and Harvey teaches or suggests the instant invention.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 102 and 103(a) are respectfully requested.

**CONCLUSION**

Reconsideration and withdrawal of the rejections of the application and prompt issuance of a Notice of Allowance are respectfully requested in view of the remarks and amendments herein and the matters discussed during the September 17, 2009 telephonic interview, for which the Examiners are again thanked for the courtesies extended.

If the Examiner believes any informalities remain in the application, which may be corrected by Examiner's amendment, or whether any other issues can be resolved by telephone interview, a telephone call with the undersigned attorney is courteously solicited.

Respectfully submitted,  
MERIAL LTD.

By: /John Esteban Ezcurra/  
Judy Jarecki-Black, Ph.D.  
Reg. No. 44,170  
Tel. No. (678) 638-3805  
Fax No. (678) 638-3350

John Esteban Ezcurra, Ph.D.  
Reg. No. 61,004  
Tel. No. (678) 638-3709  
Fax No. (678) 638-3350